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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/500,246    02/08/00    FOSTER    T    6231.N-CN1

HM12/0523

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EXAMINER

WILLIAMS, P

ART UNIT	PAPER NUMBER
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1616

2

DATE MAILED:

05/23/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/500,246

Applicant(s)

FOSTER ET AL.

Examiner

Pernell V. Williams

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2, 8, 9, 11, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "very thin" in claim 2 is a relative term which renders the claim indefinite. The term "very thin" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 8, 9, 11, 19, and 20 recite the initials "MGA" and "TBA", which render the instant claims indefinite because neither set of initials specifically delimits one single genus or species of compound.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,288,496 (Lewis) and U.S. Patent 5,654,008 (Herbert *et al.*), and further in view of U.S. Patents 4,652,441 (Okada *et al.*).

#### **Determining the scope and contents of the prior art**

Lewis discloses as essential components for a sustained drug-release system all of the following:

- Vehicles for variable release of active agent (column 4 lines 3-41); and
- Multiphasic microparticles (column 6 lines 42-48); wherein,
- The active agent may be trenbolone acetate (column 3 lines 47-55); or
- Mixtures with other active agents (column 6 lines 48-55); and also,
- Methods of using said system by injecting said microparticles.

Herbert *et al.* discloses using microparticles of trenbolone acetate (column 5, lines 30-35) combined with melengestrol in a multiphasic drug delivery system (column 17 lines 46-65), which may be injected (column 17 lines 29-46).

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Okada *et al.* discloses sustained-release compositions containing drug-retaining substances such as carbohydrates, organic acids and salts thereof, polyvinyl compounds, methylcellulose, carboxymethyl cellulose, and polyethylene compounds (column 4 lines 11-54).

### **Ascertaining the differences between the prior art and the claims at issue**

The instant application claims as essential components for a multiphasic drug delivery system injectable microparticles of trenbolone acetate combined with melengestrol.

The prior art references Lewis and Herbert *et al.* differ from the instant application in that the claims of the instant application require the use of excipients seen as disintegrating agents. The instant application, Lewis, Herbert *et al.*, and Okada *et al.* are all seen to be in the same field of endeavor which is the art of sustained drug-releasing systems.

### **Resolving the level of ordinary skill in the pertinent art**

In light of Okada *et al.*, it would have been obvious to the practitioner of ordinary skill in this art at the time the invention was made to add excipients such as carbohydrates, organic acids and salts thereof, polyvinyl compounds, methylcellulose, carboxymethyl cellulose, polyethylene compounds, because Okada *et al.* teaches that those excipients are well known to be used to aid in disseminating drug particles. Normally, changes in temperature, concentration, or other process conditions of an old process do not impart patentability unless the recited ranges are critical, i.e., they produce a new and

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unexpected result that is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality. Even though applicant's modification may result in great improvement and utility over prior art, it may still not be patentable if said modification was within the capabilities of one skilled in the art. More particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

**Considering objective evidence present in the application indicating obviousness or nonobviousness**

It is noted that there has not been presented any evidence of record to obviate the rejection cited *supra*. The disclosures of the components and methods as set forth in the prior art patents are seen to render the instantly claimed compositions and methods *prima facie* obvious. Hence, there is no evidence in the present application to support nonobviousness.

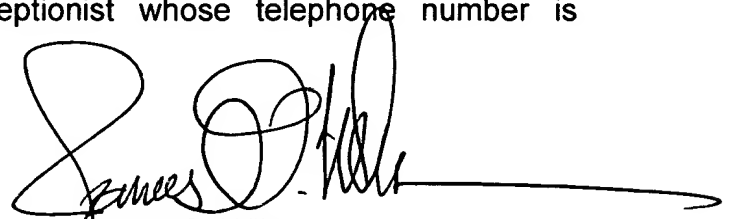
**Claims 1-25 are not allowed at this time.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pernell V. Williams, whose telephone number is (703) 308-4645. The examiner can normally be reached from 8AM to 4:30PM Monday to Thursday, and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, Examiner James O. Wilson may be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



James O. Wilson  
Primary Examiner  
Art Unit 1623



pvw  
May 22, 2000